UNITED
NATIONS

E

Economic and Social
Council

Distr.
GENERAL

E/CN.4/1999/90
15 January 1999

Original: ENGLISH

COMMISSION ON HUMAN RIGHTS
Fifty-fifth session
Item 17 (d) of the provisional agenda

PROMOTION AND PROTECTION OF HUMAN RIGHTS: SCIENCE AND ENVIRONMENT

Human rights and bioethics

Report of the Secretary-General

CONTENTS

	Paragraphs	Page
Executive summary		2
Introduction	1 - 6	3
I. LEGISLATIVE AND OTHER MEASURES TAKEN AT THE NATIONAL AND INTERNATIONAL LEVELS TO ENSURE THAT THE LIFE SCIENCES DEVELOP IN A MANNER RESPECTFUL OF HUMAN RIGHTS	7	4
A. General observations	7 - 10	4
B. Legislative, administrative and other measures aimed at protecting human rights in the bioethical context	11 - 24	5
C. Machinery for the effective promotion of ethical standards	25 - 39	7
II. CONCLUSION	40 - 42	10

Executive summary

This report draws attention to recent developments in international bioethics law. The Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of UNESCO on 11 November 1997, contains human rights standards and establishes an ethical framework for activities in this field. The United Nations General Assembly, at its fifty-third session, endorsed the Declaration.

Taking into account recent replies and those analysed in the two previous reports, it may be noted that increasing numbers of countries have enacted laws on the subject. These laws mainly deal with the application in medicine of new advances in biology and in the protection of human beings, in particular organ transplants, family planning, new human reproduction technologies and biomedical research involving human subjects. The replies received show that a legal framework exists which in principle ensures that the progress of science and technology benefits people without infringing their rights. However, there are problems of protecting the individual in the event of biomedical experimentation, especially to ensure respect for the integrity of persons participating in such research and their free and informed consent based on an assessment of the risks involved, in order to avoid any untoward incident or undesirable effect.

The machinery for the effective promotion of ethical standards includes legislation, administrative regulations, special governmental machinery, committees on ethics, safety inspections services and safety testing of new equipment. Such mechanisms exist in all States which sent replies.

In the conclusions and recommendations the Commission on Human Rights and the Office of the High Commissioner for Human Rights are encouraged to participate in the implementation of the UNESCO Declaration. The need was identified for further research into some aspects of the issue and it is recommended that developing countries be provided with specific assistance in the form of technical cooperation, transfer of technology and exchanges of information among relevant institutions and professional societies.

This report also analyses the concept of family planning from a human rights perspective as defined by relevant international conferences.

Introduction

1. At its fifty-third session, the Commission on Human Rights, in its resolution 1997/71, aware of the rapid development of the life sciences and the dangers that certain practices may pose to the integrity and dignity of the individual and seeking to ensure that scientific progress benefits individuals and develops in a manner respectful of fundamental human rights, invited Governments, the specialized agencies and other organizations of the United Nations system, in particular the United Nations Educational, Scientific and Cultural Organization and the World Health Organization, and other intergovernmental, particularly regional, organizations and non-governmental organizations to inform the Secretary-General of activities being carried out to ensure that the life sciences develop in a manner respectful of human rights and beneficial to humanity as a whole.

2. The Commission also invited Governments to inform the Secretary-General of legislative or other measures taken to this end. It further invited Governments to consider establishing independent, multidisciplinary and pluralist committees of ethics to assess, notably in conjunction with the International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organization, the ethical, social and human rights questions raised by the biomedical research undergone by human beings and, in particular, research relating to the human genome and its applications; it also invited them to inform the Secretary-General of the establishment of any such bodies, with a view to promoting exchanges of experience between such institutions.

3. The Commission also requested the Secretary-General to prepare a report on the basis of these contributions for consideration by the Commission at its fifty-fifth session. The present report is submitted to the Commission in pursuance of its resolution 1997/71.

4. Pursuant to that resolution, the Secretary-General, by a communication dated 12 June 1997, invited States and interested intergovernmental and non-governmental organizations to submit their contributions to the Office of the High Commissioner for Human Rights by 30 January 1998.

5. By 7 December 1998, replies had been received from the Governments of Croatia, Cuba, Denmark, France, Germany, Portugal and Turkey, the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the United Nations Population Fund (UNFPA).

6. Attention is drawn in this connection to the 1995 report on the same subject (E/CN.4/1995/74), which analysed measures taken by the United Nations in this field. In particular, a number of standards adopted by United Nations organs relating to human rights and bioethics were reproduced and described. That report and the 1997 report (E/CN.4/1997/66) also included replies from a number of Governments, UNFPA, two United Nations specialized agencies (UNESCO and WHO), one intergovernmental organization (the Council of Europe), two non-governmental organizations (the Council for International Organizations of Medical Sciences and the Commonwealth Medical Association) and the Institute

of Health and Law of the University of Neuchâtel. Since these materials are not reproduced in the present report, readers interested in them may wish to consult the 1995 and 1997 reports.

I. LEGISLATIVE AND OTHER MEASURES TAKEN AT THE NATIONAL AND INTERNATIONAL LEVELS TO ENSURE THAT THE LIFE SCIENCES DEVELOP IN A MANNER RESPECTFUL OF HUMAN RIGHTS

A. General observations

7. In the replies received it has been noted that the 1990s have been especially fruitful years for the development of international bioethics law. Reproductive health and rights have been firmly established and defined in international conferences, such as the International Conference on Population and Development and the Fourth World Conference on Women. It was also emphasized that reproductive rights "rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health. It also includes the right of all to make decisions concerning reproduction free of discrimination, coercion and violence as expressed in human rights documents". 1/ Reference was made to the fact that, on 19 November 1996, the Council of Ministers of the Council of Europe adopted the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Biomedicine, which marked the emergence of specifically European principles aimed at ensuring that scientific advances benefit human kind as a whole without detracting from human rights.

8. Furthermore, on 11 November 1997, the General Conference of UNESCO adopted the Universal Declaration on the Human Genome and Human Rights. The Declaration was the result of several years of work by the International Bioethics Committee of UNESCO on behalf of the international community. It is considered as a concrete contribution to the principles of the Universal Declaration of Human Rights. In its resolution 1997/15, the Sub-Commission on Prevention of Discrimination and Protection of Minorities took note of the work of UNESCO in the field of the human genome and emphasized the need for a standard-setting framework to ensure that genetic research and its application are developed in a harmonious way that demonstrates regard for human dignity, in particular for the dignity and the way of life of indigenous people.

9. Governments' replies demonstrated that beneficial coexistence between the advances of science and technology and human rights and dignity was both possible and desirable but there was a need to supervise scientific activity and to surround scientific research with legal and material safeguards, while respecting scientists' right to freedom of research.

10. The Government of Cuba considered that many human rights related to bioethics were closely linked to health care and referred to Cuban legislation on these issues.

B. Legislative, administrative and other measures aimed at protecting human rights in the bioethical context

1. Medical treatment

11. Article 5 (a) of the Universal Declaration on the Human Genome and Human Rights provides that research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risk and benefits pertaining thereto and in accordance with any other requirement of national law. In cases of interventions on persons who do "not have the capacity to consent", "consent or authorization shall be obtained in a manner prescribed by law, guided by the person's best interest" (art. 5 (b)). This applies especially to sick or very young children, elderly persons or persons with mental illness.

12. The Government of Cuba reported on the health care provided to its population, operating in conformity with universally accepted ethical standards.

2. Medical research involving human beings and experiments on human subjects

13. Article 5 (c) of the Declaration provides for "the right of each individual to decide whether or not to be informed of the results of genetic examination ..." while paragraph (d) provides that "in the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines".

14. Article 7 of the Declaration states that "genetic data associated with an identifiable person and stored or processed for the purposes of research ... must be held confidential in the conditions set by law". This principle complements the principles and norms of confidentiality set forth in article 12 of the Universal Declaration of Human Rights, article 17 of the International Covenant on Civil and Political Rights and the Guidelines for the Regulation of Computerized Personal Data Files.

15. According to article 10, "no research or research applications concerning the human genome ... should prevail over respect for human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people". Article 11 prohibits practices which are contrary to human dignity, such as reproductive cloning of human beings. Article 12 (b) states that freedom of research is part of freedom of thought. It further provides that the applications of research, including in biology, genetics and medicine, concerning the human genome, should seek to offer relief from suffering and improve the health of individuals and humankind as a whole.

16. In order to minimize high-risk experiments, the Government of Germany stated that the primary functions of an ethics committee included protecting patients and subjects from hazardous research, mainly by minimizing exposure to and prohibiting or restricting high-risk experiments. In addition, the ethics committee had the task of protecting researchers by preventing them from embarking on projects that were questionable from a legal and ethical point of view.

17. In Turkey, regulations relating to the ethical aspects of clinical research on drugs in which human subjects are involved were elaborated by the Ministry of Health. According to the Law on Basic Health Services of 7 May 1987, such research is conditional upon the consent of an individual and the permission of the Ministry. All research carried out on living organisms, especially the one carried out on human beings, were under the control of ethics committees.

3. Family planning: artificial insemination and abortion

18. Family planning is a basic human right as defined in a number of human rights instruments analysed in previous reports. The World Population Plan of Action, adopted by the 1974 World Population Conference in Bucharest, extended this right to "all couples and individuals". The Programme of Action of the 1994 International Conference on Population and Development (ICPD) states: "The aim of family planning programmes must be to enable couples and individuals to decide freely and responsibly the number and spacing of their children and to have the information and means to do so and to ensure informed choices and make available a full range of safe and effective methods ... . The principle of informed free choice is essential to the long-term success of family planning programmes. Any form of coercion has no part to play" (para. 7.12).

19. UNFPA pointed out that in the past 20 years, countries worldwide dramatically expanded the availability of family planning services, accelerating a decline in fertility rates. At the same time, it referred to what it considered a mistaken notion that family planning meant promotion of abortion. This was totally incorrect since family planning helped prevent the need for abortion. It emphasized that abortion was not a method of family planning and it did not support abortion in any country.

20. The ICPD urged countries "to deal with the health impact of unsafe abortion as a major public health concern and to reduce the recourse to abortion through expanded and improved family planning services" (para. 8.25). It called on Governments "to take appropriate steps to help women avoid abortion ... and in all cases provide for the humane treatment and counselling of women who have had recourse to abortion" (para. 7.24).

21. As pointed out in the two previous reports, there are reproductive rights that are already recognized in national laws and international human rights instruments. 2/ Both the ICPD and the Fourth World Conference on Women further elaborated and defined those rights. Both conferences also stated that reproductive health was a broad concept that included more than family planning, e.g. pre- and post-natal care, safe delivery, infant and women's health care; prevention and appropriate treatment of infertility; prevention of abortion and the management of the consequences of abortion; treatment of reproductive tract infections, sexually transmitted diseases and other reproductive health conditions; and information, education and counselling, as appropriate, on human sexuality, reproductive health, and responsible parenthood. 3/

4. Developments in biotechnology

22. Attention was drawn to the working paper presented by Mr. Osman El-Hajjé to the Sub-Commission on Prevention of Discrimination and Protection of Minorities in 1997, which dealt with the potentially adverse consequences of scientific progress in respect of the integrity, dignity and human rights of the individual (E/CN.4/Sub.2/1997/34). The paper states that advances achieved in the fields of life and health sciences and the awareness of their human implications have marked the end of this century, at a time when man is able to combine his knowledge with the power to change the development of species, including his own, by using the latest discoveries in genetics and embryology. In his view, in recent years, some scientific advances have been misused. One such example is facilitating pregnancies in women beyond the natural age of procreation and the possible consequences of this practice for a child's parentage and rights.

23. The paper also mentions genetic applications in the area of prenatal or pre-implant diagnosis. It states that in order to preserve the human species, it would be preferable to use gene therapy with caution, restricting it to somatic (body) cells, with the exclusion of germ cells (i.e. the cells used for sexual reproduction). Recent genetic research leading to the creation of mammal clones gave rise to mixed feelings, since it raised questions not only about man's dignity, but also about his social ties. This type of research might create two types of human beings: the real one and the clone, with all the consequences one might imagine. It would therefore appear necessary to assert the primacy of man over science when consideration is given to studies into the human embryo, man himself or his genome.

24. Cuba reported that interest in bioethics has grown considerably since the late 1980s. A new university course entitled "Health technology" was introduced in 1989 and included a full semester devoted to bioethics. It covers the following issues: ethical dimension of public health; education and communication as an ethical question in the domain of health; ethics and humanity in the relationship with a healthy person; professional error and confidentiality; impact of the scientific and technical revolution on health care; bioethical problems at the beginning and end of life; and quality of health services. In 1994, a multidisciplinary group of university teachers was established in Cuba to promote bioethics in medical schools and to design an intensive course on general bioethics.

C. Machinery for the effective promotion of ethical standards

25. The methods adopted or proposed for the promotion and protection of human rights at the national level and relating to the issues dealt with in the present report were analysed extensively in the previous reports. Those methods included legislation, administrative regulations and licensing of devices, official guidelines, special governmental machinery, codes of ethics, science policies, economic policies, safety inspection services and safety testing of new equipment.

26. According to articles 51 and 52 of the Law on Medical Protection of Croatia (published in the Official Gazette, No. 1/97), commissions on ethics are established in medical institutions with the task of ensuring that their

work is based on the principles of medical ethics and deontology. The law also defined the scope of the competence of those bodies. The Commission on Ethics and Deontology of the Croatian Medical Association participated in regional activities concerning bioethics, including a meeting of national committees on bioethics in Paris and in the signing of a document on the prohibition of human cloning with other European States.

27. In addition, in one of the earlier reports (E/CN.4/1199/Add.1, paras. 170 and 172) attention was drawn to the fact that national mechanisms were necessary for assessment - including the assessment of possible side-effects and long-range effects - of whether the time was right for particular innovations and whether their advantages outweighed for the society the discernible disadvantages. The Secretary-General has received additional information and comments on a number of these issues.

28. The Government of Cuba reported that at all levels of the National Health system operating in the country there were medical ethics committees which ensured observance of patients' rights. Chairs of bioethics had been established with the aim of organizing the ethical training of Cuban specialists in this sphere. At the end of 1993, work was completed on the draft Code on the Professional Ethics of Scientific Workers. This Code coincides in its essential aspects with universally accepted principles and standards. In 1996, the Standing Commission on Ethics of the Cuban Academy of Sciences was established which became the steering group of the Cuban Committee of Ethics, affiliated with the Cuban National Commission for UNESCO.

29. In 1993, the Ministry of Health of Cuba established a national centre for clinical testing with a 'review and ethics committee' to supervise research projects. Also in 1993, the bioethics sections of the Cuban Scientific Society for Legal Medicine were established and a workshop was held on ethics and genetics. A multidisciplinary bioethics group was established within Hermanos Ameijeiras hospital. The Cuban Code of Ethics and the work of the committees on medical ethics needed to be updated and perfected.

30. In Denmark, a system of scientific ethical committees has existed since 1979, based on the principles of the Declaration of Helsinki. 4/ Act No. 503 of 24 June 1992 on the Scientific Ethical Committee System and Handling of Biomedical Research Projects was amended by consolidated Act No. 221 of 4 March 1997. 5/ The scientific ethical committee system consisted of a number of regional committees and a central committee. The committees were independent and included professionals as well as lay members.

31. The Danish law ensured that biomedical scientific projects involving human beings could not be initiated before the regional committee had given its approval, in order to secure the protection of persons participating in scientific projects. The law strongly underlined that the committees had to ensure that the possible risks connected with the project had been thoroughly analysed.

32. The Government of Germany pointed out that the functions of ethics committees are regulated by a number of provisions of different federal laws. For instance, in accordance with section 40 of the Federal Drug Law of 1995, the commencement of a clinical trial of a pharmaceutical product on human

beings required prior approval by an independent ethics committee established under Länder law. In addition, pursuant to section 17 of the Medical Devices Act, clinical trials may only be started when the approval of an ethics committee has been obtained of the plan of research. Subsection 7 of section 17 of the Act stipulates that the ethics committee must be an independent, multidisciplinary body registered with the competent higher Federal authority. Both laws established that in the absence of approval from an ethics committee, clinical trials could only be commenced if the competent higher Federal authority had not objected within 60 days of examining the documentation.

33. The Standard Professional Code of German Doctors, adopted in 1988, requires physicians intending to conduct clinical trials on human beings or to carry out epidemiological research to obtain counselling from an ethics committee on any questions of professional ethics and law the project may give rise to. In addition, a physician had to be heard by an ethics committee before embarking on any research involving human gametes and living embryonic tissue. In 1995, the Federal Medical Society established a Central Commission for the Safeguarding of Ethical Principles in Medicine and Related Areas. The tasks of that Commission included, in particular, the following:

(a) Making statements on ethical questions stemming from the advances and technological developments in medical science and related areas that are valid throughout the Federal Republic of Germany; and

(b) Commenting on issues that are of fundamental importance to the ethical aspects of the duties emanating from the exercise of the medical profession.

34. The French Government sent a list of laws on medical treatment in the bioethical context, organ transplantation, biomedical research involving human subjects and new human reproduction technologies, and the texts of laws relating to the national mechanisms dealing with bioethical issues. 6/ The body of French laws in the field of bioethics is considered quite comprehensive. A number of texts adopted between 1988 and 1997 were incorporated into the Civil Code, the Public Health Code and the law on information technology and freedom. The French legislation covers most issues in respect of the subject matter except euthanasia and reproductive human cloning.

35. By decree No. 97-555 of 29 May 1997, the National Consultative Committee for Ethics in the Life Sciences and Health was established. Article 4 of the decree provides that the Committee may be informed of a situation by the President of the National Assembly, the President of the Senate or a member of the Government, as well as by an institute of higher education, a public institution or a foundation recognized as working in the public interest and whose principal activity is research, technological development or the promotion and protection of health. It can also decide to take up questions brought by persons other than those mentioned or by one or more of its members. Within the context of its mission the Committee organizes each year a public conference on ethical problems in the fields of the life sciences and health.

36. The Portuguese Government attached a list of laws demonstrating that the ethical standards which have human rights components are enforced through the operation of law and are supervised by special governmental machinery, in particular by the Ethical Commissions for Health. 2/

37. In Turkey, the Ministry of Health put into effect a Directive of 1993 that regulates the ethical, administrative and practical aspects of drugs-related trials on human subjects. As a part of its implementation a Central Ethical Committee was set up at the Ministry. It was supplemented by local ethical committees at each medical school and training hospital. At present, there are 45 local ethical committees. The ethical committees are charged with protecting the rights, integrity and welfare of the volunteers involved in drug trials. In particular, they control human experimentation and protect human personality from dangers related to it in accordance with principles embodied in the Declaration of Helsinki. In addition, research ethics committees which work under the guidance of the Central Ethics Committee are being established in universities and State hospitals. In an institution where a research ethics committee exists it is requested to approve all clinical drug research.

38. There are two other kinds of committees in Turkey. One is the Ethics Committee of the Turkish Medical Association, which was established to determine the attitudes of the Association towards ethical issues, and the other is the Hospital Ethics Committee, which is being established now. The revision and clarification of the aims, structures and functions of these institutions is thought to be necessary.

39. Attention may be drawn to UNESCO General Conference resolution 29 C/Resolution 17 of 11 November 1997, entitled "Implementation of the Universal Declaration on the Human Genome and Human Rights". In particular, in paragraph 1 (a), the General Conference urged member States, in the light of the provisions of the Declaration, to take appropriate steps, including the introduction of legislation or regulations, to promote the principles set forth in the Declaration and to promote their implementation. The resolution provides for a number of other measures to implement the Declaration, in particular defining the tasks of the International Bioethics Committee to ensure follow-up to the Declaration.

II. CONCLUSION

40. The adoption of the Universal Declaration on the Human Genome and Human Rights and the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Biomedicine demonstrates that the rapid development of science and its technological applications have been accompanied by the emergence of specific international principles aimed at ensuring that scientific advances benefit human rights and protect human dignity.

41. A positive development at the national level is the establishment of ethics committees to supervise scientific activity, to foresee and prevent possible excesses, to alert the authorities and public opinion, and to act in an advisory capacity to assist public authorities as well as scientific researchers and their professional organizations.

42. Further standards are likely to be elaborated and mechanisms established at the international level, especially to ensure that genetic research and its applications are developed in a harmonious way that demonstrates regard for human rights and dignity, particularly of vulnerable groups of people.

Notes

1/ Programme of Action of the International Conference on Population and Development (ICPD), para. 7.3. In Report of the International Conference on Population and Development, Cairo, 5-13 September 1994 (United Nations publication, Sales No. E.95.XIII.18).

2/ See E/CN.4/1995/74, para. 101.

3/ See ICPD Programme of Action, paras. 7.2 and 7.6.

4/ In the principles, see E/CN.4/1995/74, paras. 65-67.

5/ Available for consultation in the files of the secretariat.

6/ Ibid.

7/ Ibid.